

NISBET OYSTER CO., INC.

P.O. BOX 338
BAY CENTER, WA 98527
360-875-6629
360-875-6684 FAX

7452 '00 JUL 21 P1:48

CULTIVATORS • PROCESSORS • PACKERS • PACIFIC NORTHWEST OYSTERS

16 July 2000

Dept. Health and Human Services
Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers lane
Rockville, MD 20852

RE: Docket No. 00N-1351
21 CFR part 101
Food Labeling; Use of the Term "Fresh" for Foods Processed With Alternative
Nonthermal Technologies; Public Meeting

Dear Sirs, Madams,

Our company is a farm as well as a processor of Pacific oysters located on Willapa Bay in Southwest Washington State. Willapa Bay is the largest producer of Pacific oysters on the West Coast of North America with annual production of approximately 500,000 gallons of shucked meats as well as live sold inshell.

We are a processor in the sense that we take oysters from our farm as well as buy oysters from other farms, shuck them, subject the meats to a fresh water wash, grade to size and pack them in various size containers from 8oz. To 128oz. and sell to distributors for resale at the retail food level as well as food service. This is about 70% of our business. This pack is almost entirely sold and labeled as fresh with a shelf life under refrigeration of approximately two weeks. All of our oysters currently are shucked by hand. The other 30% of our business is selling oysters live in the shell to the same markets.

We are a small business with sales of about 2.8 million annually.

The reason for this letter is to inform you of our views on nonthermal technologies, specifically High Hydrostatic Pressure Processing.

After 2 years of conjunctive research with Oregon State University's Seafood Laboratory we have concluded that whole live oysters in the shell when subjected to certain high hydrostatic pressures will;

1. Cause the adductor muscle to cleave or release from the shell thus effectively shucking the oyster.

00N-1351

C 1

2. Effectively reduce or eliminate bacteria loads as well as certain vibrios and other microorganisms at specific hydrostatic pressures and durations.

This nonthermal process results in shucked oyster meats as well as oysters in the shell that we consider to still be "fresh" in every aspect. The resulting product is virtually indistinguishable from handshucked meats, yet with definite food safety advantages with microbial reductions.

This is an important point with when it comes to molluscan shellfish as a vast part of our market consumes their shellfish in a raw, uncooked, fresh state. The term "fresh" is important to the consumer in that it denotes the product is not heat processed or cooked and that the product is not shelfstable, is relatively close to the harvest date and must be kept under refrigeration.

Pressure processed product exudes all the same characteristics. It still must be refrigerated and thus is considered to be fresh when consumed by the code or sell by date printed on the container. All "fresh" characteristics of the product remain unchanged.

Responses to specific questions asked in the Notice of Public Meeting dated 7/3/00:

1. Do consumers associate the term "fresh" with organoleptic characteristics, nutritional characteristics, or some other characteristics.

Yes, consumers of fresh oysters are acutely aware of the sensory qualities associated with the product. Preliminary and ongoing studies underway indicate that the organoleptic and nutritional qualities of oysters are unchanged with the application of high pressure at the parameters used for processing.

2. Do consumers want a way to identify foods that taste and look fresh but have been Processed to control pathogens.

Raw protein foods when consumed may pose a risk of illness. We believe consumers do want to know their shellfish is safe and thus would want to know if the product has been processed to control pathogens. The analogy here is raw versus pasteurized milk. They are both labeled and considered fresh, but consumers want to know what they are buying.

A further determination should be done to see if under certain processing parameters high pressure could be considered a "cold pasteurization" process.

3. What does the industry think the term "fresh" means.

Our companys views are that the term "fresh" denotes;

1. The oyster is in a raw state, uncooked and not subject to heat processing.
2. The product has a definite shelf life within weeks of the harvest date.
3. The product must be kept under refrigeration.

5. Do the new technologies preserve the foods.

High Hydrostatic Pressure technology when applied to oysters does not create a preserved or shelfstable food in our application of the technology.

6. Are the new technologies truly nonthermal.

Yes. Testing on vessels used in the High Pressure process has shown that there is virtually no discernable raise in temperature as a result of this process either in the surrounding water medium or in the oyster itself.

7. Are their quantifiable parameters, e.g. level of nutrients, vitamins etc. that could be measured to determine if a food is fresh.

Yes, we believe there is and are in the process of identifying those parameters.

8. Is there a term other than "fresh" that can be used for foods processed with the new Technologies.

With regards to our fresh oyster products, no, "fresh" must be used with our product.

9. Would consumers understand a new term.

We believe a new term would not work for our product in that "fresh" has long been associated with shellfish and seafood in general. The publics perception is that fish and shellfish purchased at a retail store must be considered fresh if to be of quality.

10. What is the economic impact of allowing use of the term "fresh" for foods processed with the new technologies.

Continued use of the term "fresh" while using High Pressure technology is of paramount importance to our company and the industry. "Fresh" is central to our label and enables us to project a healthy product that is indeed wholesome and fresh. The product is fresh.

We need continuum in being able to market our product in the traditional manner while employing High Pressure technology for processing. It is vital to our companys financial health.

11. Would the term "fresh" on foods processed with new technologies place small firms not able to use these technologies at an economic disadvantage.

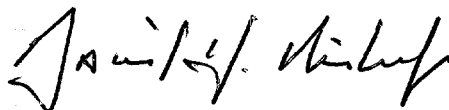
No, we are considered a small company. Our label would not read differently than a label from a handshucked product in the sense they are both fresh products and the costs of the technology to the company is an offset to labor handshucking costs. The technology would not undercut existing producers and processors without this technology.

In summary, we as a producer of shellfish products are concerned with our fresh markets and the quality aspect of the food product we produce. We believe shellfish consumers and the public in general has concerns over the safety of oysters and if incidental illness is lowered with regards to raw shellfish consumption due to new processing technology then public perception will be buoyed and enhanced. Our fresh oysters carry a American Heart Association Endorsement and are considered an excellent high protein, low fat, mineral rich food source.

It is our belief that this technology will be in the best interest of our customers as well as our companys continued survival and ask that the term "fresh" be included in this new High Pressure processing technology for oysters.

Please feel free to contact me for any questions.

Very sincerely yours,

A handwritten signature in dark ink, appearing to read "David H. Nisbet". The signature is fluid and cursive, with a large initial "D" and a stylized "N".

David H. Nisbet
President
Nisbet Oyster Co., Inc.

ISLET OYSTER CO., INC.
PO BOX 538
Say Center, WA. 98527



DOCKETS MANAGEMENT BRANCH
(HFA-305)
Food & Drug Administration
Rm. 1061
5630 FISHERS LAKE
Rockville, MD

20852

